



**MONTANA DEPARTMENT OF CORRECTIONS
CLINICAL SERVICES DIVISION
PROCEDURE**

Procedure No.: CSD 4.5.11A	Subject: HEPATITIS C TREATMENT	
Chapter 4: FACILITY/PROGRAM SERVICES		Page 1 of 7 and Attachments
Section 5: Clinical Services		Effective Date: 12/23/2016
Medical Director Signature: /s/ Tristan Kohut, MD		Revised:
Clinical Services Division Administrator Signature: /s/ Connie Winner		

I. PURPOSE

The Clinical Services Division of the Department of Corrections, using evidence-based clinical guidance, will provide appropriate monitoring for all Hepatitis C Virus Antibody + (HCVAB) / Hepatitis C Virus + (HCV) offenders, and will provide HCV antiviral drug treatment when determined by clinical indication and/or treatment criteria.

II. DEFINITIONS

Medical Review Panel (MRP) – A panel of qualified health care professionals that is comprised of the Clinical Services Division administrator, medical director, at least two additional health care providers (one of whom must be a physician), and the Department managed care RNs, all of whom are designated to review complex health care cases and health care topics relevant to the patient population under the care and custody of the Department of Corrections.

Mountain Pacific Quality Health Foundation (MPQHF) – A federally designated Quality Innovation Network-Quality Improvement Organization (QIN-QIO) providing drug utilization review services to the Clinical Services Division of the Department of Corrections.

III. PROCEDURES

A. Screening and Education

1. All incoming offenders at all secure facilities are offered education about HCV utilizing the [Hepatitis C: Get the Facts](#) publication and the [HIV and Hep C](#) presentation.
2. All incoming offenders at all secure facilities are offered HCV antibody (HCVAB) screening. If the screening is positive, confirmatory testing by laboratory diagnostic services will be done.
3. Offenders will not be retested while they remain in Department custody unless there are clinical indications or if the offender has a specific history of exposure while incarcerated that suggests need.
4. If an offender is readmitted after a time in the community, they may be retested at the discretion of the provider or advised to obtain testing upon release.
5. All HCVAB+ offenders will be entered into the facility tracking spreadsheet.
6. All offenders found to be HCVAB+ will receive additional testing to determine viral load, and liver fibrosis (Fib-4).

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7. If an offender self-reports HCVAB + status this will be verified by medical records or the offender will be re-tested and pending the results will receive additional testing to determine viral load and Fib-4.
8. At initial intake, nonspecific and transitory elevations of liver function tests (LFTs) are often seen. These are usually the residual of alcohol and drug use and lifestyle issues. Elevated LFTs obtained during the first six months after the initiation of sobriety will not be interpreted as evidence for ongoing liver inflammation secondary to HCV infection unless there are clinical signs and symptoms to cause concern. A follow up Fib-4 will be obtained 6-8 months after intake and then annually.
9. All HCVAB+ offenders will be offered vaccination against Hepatitis A and B (Twinrix), regardless of expected length of stay, unless previous infection or vaccine has been documented or the provider believes that vaccination is unnecessary or contraindicated.
10. Offenders will be provided with a card listing the dates and types of immunizations they received. Offenders discharging prior to completion of a vaccine series will be provided information to access the health department where they will be relocating.
11. Lifestyle changes such as exercise, good diet, appropriate weight, and abstaining from drugs and alcohol can help prevent the progression of HCV. Health care staff will assist offenders in identifying lifestyle changes appropriate to their age, medical conditions and abilities.

B. Diagnosis

1. When evaluating for treatment, offenders are categorized into the following categories:
 - I. Never infected, HCVAB–;
 - II. Infected but not viremic, HCVAB+/virus– (i.e. "cleared");
 - III. HCVvirus+, but anticipated incarceration too short for treatment and/or treatment not desired;
 - IV. HCVvirus + but no or slow progression anticipated; or
 - V. HCVvirus + and potential treatment candidate.
2. Groups I-III do not need to be monitored, but all Group II offenders will be entered in the facility Hepatitis C database for statistical purposes with a note "no viral load", and Group III offenders will be entered in the facility Hepatitis C database for statistical purposes with a note "not eligible for treatment," or "treatment not desired". Group III will have a note in their medical record indicating the reason.
3. If Fib-4 is >2 in two elevations over a year, not including the initial months of incarcerations, significant ongoing liver inflammation is present. One elevation is sufficient if the offender has other clinical indications for work-up. These offenders require work-up to:
 - a. identify alternative causes of liver disease;
 - b. identify the extent of liver disease and specifically whether decompensated cirrhosis is present;

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- c. identify contraindications to medication therapy for HCV; or
- d. identify social and demographic characteristics that may lead the attending provider to either support or not support medication therapy aimed at HCV.

C. Treatment

1. Treatment will be individualized, in consultation with the Department Medical Director, MRP, with pre-authorization review by Mountain Pacific Quality Health, and at times involves an external Infectious Disease Specialist.
2. Initial assessment of suitability for treatment will be completed by the provider at the facility housing the offender. A [HCV Treatment Pre-Authorization](#) form will be completed and submitted to CORMedical@mt.gov.
3. Each secure care facility will be responsible for initiating the treatment request, providing treatment, and monitoring during the treatment period. Following conclusion of treatment, continued monitoring, testing and data reporting by each facility is required. Each facility is responsible to submit required data to CorMedical@mt.gov.
4. The MRP will review all information about an offender recommended for treatment. The MRP may request additional information, recommend additional diagnostic testing, recommend continued monitoring of offender or forward the [HCV Treatment Pre-Authorization](#) form to MPQH for secondary review. MPQH will:
 - a. recommend drug regimen approval as submitted;
 - b. recommend drug regimen approval subject to additional evidence-based clinical requirements; or
 - c. recommend denial with supporting clinical rationale.
5. If the provider chooses a non-formulary drug treatment, the provider must document justification and resubmit to MRP for a second review and determination.
6. Pending review by MPQH, the treating physician or designated mid-level provider will again discuss all aspects of treatment with the offender and have the offender sign the [HCV Treatment Pre-Authorization](#) form acknowledging treatment requirements and offender expectations. The offender's treatment period and follow-up will be monitored by the treating provider only.
7. The appropriate medication will be used, taking into consideration risk of side effects, length of treatment, genotype, cost, etc. Each Direct Acting Antiviral has a protocol for treatment which should be followed. All treatment will be Directly Observed Therapy. All offender treatment issues and concerns will be directed to the offender's treating provider.
8. Offenders who are receiving HCV drug treatment will be monitored during treatment in the following manner:
 - a. treating provider will monitor using the treatment tracking flowsheets regarding intervals for CBC, creatinine, LFT, TSH, and high sensitivity HCV viral load;
 - b. treating provider will assess for depression and other side effects at each visit;

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- c. treating provider will follow-up as clinically indicated, usually every 1 – 4 weeks during active treatment; and
 - d. treating provider will ensure the 12-week test of cure (SVR 12) is performed and results submitted to MPQH and CorMedical@mt.gov
- 9. All treatment and monitoring related forms, information and data will be included in the offender's medical record.
- 10. Offenders with HCV disease who will be discharging prison in less than 18 months after the physician has established the presence of ongoing liver inflammation will generally not be candidates for medication therapy during confinement. These offenders will be counseled regarding the risks and benefits of therapy and the need to receive therapy after release from prison. Exceptions will be offenders whom the physician recommends for work-up for clinical reasons. However, in no case will medication therapy be initiated if that therapy cannot be completed, including 12-week test of cure.
- 11. Offenders receiving treatment prior to and upon entry to prison will not have the treatment interrupted unless the physician believes that continuing treatment is not in the offender's best interest. If there is reason to suspect the offender has not been compliant with medication immediately prior to prison placement (i.e. stopped in jail), or if behavior preceding incarceration included high risk activities, the continuation should be discussed with the offender's community physician and Department medical director.
- 12. Department community corrections facility offenders will not be eligible for treatment except under special clinical circumstances because of their short length of stay. These offenders will be referred to community resources for follow-up and treatment determination after release. However, should an offender be transferred to community corrections during treatment, it will be continued.
- 13. Treatment should not be initiated on the basis of abnormal blood tests alone. Multiple imaging possibilities exist to determine state of fibrosis and rule out other pathology. Transient elastography (TE) is a noninvasive, highly reproducible technique for assessing the degree of liver fibrosis. Treatment decisions should never be based on one test. However, if clinical criteria are clear, the offender may be presented to the MRP for treatment without confirmatory tests.
- 14. Offenders who failed treatment with older, less effective regimens may be considered for retreatment. These offenders will be evaluated as above, except old records may replace repeat studies as appropriate.

D. Treatment Considerations

- 1. Offenders for whom medication therapy is contemplated will evidence characteristics consistent with the following **inclusion** criteria:
 - a. the offender is well informed regarding the disease and proposed therapy;
 - b. the offender is willing and competent to sign informed consent for treatment;
 - c. previous treatment is documented (affects choice of drug and time of treatment);

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- d. no evidence of HCV risk behavior or correctional issues in previous six months, including prison tattoos;
 - e. offender agrees to illicit drug screening at the provider's discretion before and during treatment;
 - f. medical and mental health concerns have been addressed and corrected if necessary;
 - g. offender is expected to attain reasonable benefit from treatment as indicated by improved quality of life or life span;
 - h. priority will be given to offenders with advanced fibrosis stage 3-4;
 - i. offenders less than or equal to stage 2 fibrosis will not be treated except with MRP permission for special considerations;
 - j. treatment is usually indicated for HCVvirus +/HIV+, HCVvirus +/HEPB+, and nephrotic syndrome, however, this needs to be reviewed annually as evidence is changing the guidelines for HCV management as new drugs are approved.
2. Offenders will likely not be provided treatment with medication if they evidence the following **exclusion** criteria; however, the decision will be reevaluated if the condition improves or the provider has other criteria to recommend treatment:
- a. clinical signs of liver failure or decompensated cirrhosis, any history of ascites, variceal bleeding, hypersplenism, hepatic encephalopathy, etc. (it may be necessary to do further testing like EGD to R/O varices, U/S of spleen, serum ammonia);
 - b. serious anemia of any cause (hemoglobin below 12g percent in men and below 11g percent in women) or bone marrow compromise indicated by neutrophils below 1500 or platelets below 100,000;
 - c. creatinine clearance greater than the upper limit of normal (needs nephrology consult to clear);
 - d. serious cardiac disease;
 - e. serious cerebrovascular disease;
 - f. poorly controlled thyroid disease;
 - g. poorly controlled blood dyscrasias;
 - h. poorly controlled cancer;
 - i. poorly controlled seizures;
 - j. poorly controlled diabetes mellitus (hemoglobin A1C > 8.5);
 - k. presence of retinopathy;
 - l. HIV infection with CD4 count <200 cells/ml or undergoing treatment for opportunistic infection;
 - m. other serious illness that is not well controlled;
 - n. continuing or recent (previous six months) treatment of a serious mental disorder, especially including psychosis producing disorders or depressive disorders, unless clearance has been received from a psychiatrist and the offender will be followed during treatment;
 - o. history of documented abuse of drugs or alcohol within the preceding 24 months, expectation that injection drug or alcohol use will resume upon release from incarceration or failure to successfully complete substance abuse therapy;
 - p. pregnancy or refusal to avoid pregnancy during and for at least six months after cessation of therapy (two methods of birth control used simultaneously must be intended);

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- q. history of non-adherence to medical therapy during the previous two years;
- r. history of non-cooperation with provision of other secure facility services; or
- s. inability to give informed consent.

E. Monitoring

1. For simplicity of protocol, the Fib-4 is recommended for monitoring. Fib-4 is calculated on AST/ALT/age and platelets and is a good predictor of the progression of HCV. The goal of clinical staff is to identify offenders with stage 3-4 fibrosis or inflammation.
2. All HCVAB +/-viral load + offenders will have a Fib-4 calculated annually as long as they are held in a secure facility.
3. The facility tracking sheet will show up to 3 Fib-4 scores, including:
 - a. intake;
 - b. 6-8 months after intake; and
 - c. annual if offender has been incarcerated 12 – 18 months or more. Preceding annual Fib-4s will be replaced by current Fib-4.
4. Category IV offenders who are HCVvirus + with Fib-4 <2:
 - a. A single determination will not reliably determine liver inflammation; serial determinations can provide guidance regarding the likelihood of the development of late-stage HCV complications. Therefore, the annual Fib-4 results, monitored by a designated provider is adequate.
 - b. If a Fib-4 is >2 after the initial six-month period and if the offender has at least 18 months remaining in incarceration and desires treatment, the offender will be advanced to the Category V group.
 - c. Ultrasound every 6 months with clinically diagnosed or biopsy proven cirrhosis to screen for hepatocellular carcinoma.
5. Category V offenders who are HCVvirus + with Fib-4 >2:
 - a. When Fib-4 becomes >2 it should be entered into the facility tracking system and the offender highlighted as a potential treatment candidate. Thereafter, every year Fib-4 will be entered on the facility tracking sheet and studied by a physician or designated mid-level practitioner to identify offenders with signs of progression.
 - b. When moved to Category V, the offender must be seen by a provider to discuss their general health, inclusion and exclusion criteria, desire for treatment, anticipated length of incarceration, etc.
 - c. Special attention should be paid to other causes of liver disease or behaviors (i.e. Tylenol ingestion) that might be exacerbating the condition.
 - d. Offender will be screened for decompensated cirrhosis, evidenced by encephalopathy, ascites, variceal hemorrhage, spontaneous bacterial peritonitis, hepatopulmonary or hepatorenal disease, or a Child-Pugh score of > 7.
 - e. The [*HCV Treatment Pre-Authorization*](#) form will be initiated.
 - f. If a determination is made to not treat, every 6 months Fib-4s will be conducted and entered on the facility tracking sheet and reviewed by a physician or designated mid-level to identify offenders with signs of progression.

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- g. If a determination is made to not treat, every 6 months imaging will be done and entered on the facility tracking sheet and reviewed by a physician or designated mid-level to screen for hepatocellular carcinoma and varices.

V. CLOSING

Questions concerning this procedure should be directed to the Department Medical Director or the Clinical Services Division Medical Bureau Chief.

VI. REFERENCES

- A. 53-1-203, MCA
- B. *DOC Policy 4.5.11 Infection Control Program*

VII. ATTACHMENTS

[HCV Treatment Pre-Authorization](#)
[Hepatitis C Database Template](#)
[Hepatitis C: Get the Facts](#)
[HIV and Hep C Presentation](#)
[Standing Orders for Hepatitis C Positive Patients](#)